

### **DETAILED ACTION**

1. Claims 20-32, 34 are pending in the current application. This is a National Stage of PCT/JP04/09272, filed 6/24/2004.
2. A supplemental restriction is required due to several factors. Firstly, depending on the meaning of variables  $X_1$  through  $X_3$ , the inventions of claim 20 can be classified into various subclasses within class 544 and 546. For example if two of the variables are N, the class is 544. Within class 544, depending on the distance of one N to the second N, the subclass is different. If the ring is pyrazine, the subclass is 336, and if the ring is pyrimidine, the class is 242. In addition, after 102 and 103 analysis of the structure, the broad structure is difficult to run in batch or normal mode in STN because of possibilities for each of the variables in formula I.
3. As a result of this new restriction, the restriction dated 5/3/07 is superceded by this restriction.

### ***Election/Restrictions***

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 20-31, and 34, drawn to compounds of formula I where the combination of variables  $X_1$ ,  $X_2$ , and  $X_3$  form a pyrimidine ring and variable W is piperidine.

Group II, claim(s) 20-31, and 34, drawn to compounds of formula I where the combination of variables  $X_1$ ,  $X_2$ , and  $X_3$  form a pyrimidine ring and variable W is pyrrolidine.

Group III, claim(s) 20-31, and 34, drawn to compounds of formula I where the combination of variables  $X_1$ ,  $X_2$ , and  $X_3$  form a pyridine ring and variable W is piperidine.

Group IV, claim(s) 20-30, and 32, drawn to compounds of formula I where the combination of variables  $X_1$ ,  $X_2$ , and  $X_3$  form a pyridazine ring and variable W is piperidine.

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Group V, claim(s) 20-30, and 32, drawn to compounds of formula I where the combination of variables  $X_1$ ,  $X_2$ , and  $X_3$  form a pyrazine ring and variable W is piperidine.

Group VI, claim(s) 20-30, and 32, drawn to compounds of formula I not covered by groups I-V.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

(f) "Markush practice" The situation involving the so-called Markush practice wherein a single claim defines alternatives (chemical or non-chemical) is also governed by PCT Rule 13.2. In this special situation, the requirement of a technical interrelationship and the same or corresponding special technical features as defined in PCT Rule 13.2, shall be considered to be met when the alternatives are of a similar nature.

(i) When the Markush grouping is for alternatives of chemical compounds, they shall be regarded as being of a similar nature where the following criteria are fulfilled:

(A) All alternatives have a common property or activity; and

(B) (1) A common structure is present, i.e., a significant structural element is shared by all of the alternatives; or

(B) (2) In cases where the common structure cannot be the unifying criteria, all alternatives belong to a recognized class of chemical compounds in the art to which the invention pertains.

In paragraph (f)(i)(B)(1), above, the words "significant structural element is shared by all of the alternatives" refer to cases where the compounds share a common chemical structure which occupies a large portion of their structures, or in case the compounds have in common only a small portion of their structures, the commonly shared structure constitutes a structurally distinctive portion in view of existing prior art, and the common structure is essential to the

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common property or activity. The different variables  $X_1$ ,  $X_2$ , and  $X_3$  and W, resulting in compounds that have achieved a different status in the art, and thus are drawn to an improper Markush group on the grounds of lack of a common nucleus. Thus lack of unity is apparent.

A preliminary search of a selected core gave numerous iterations, see below:

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=> d que sta
L1          STR

  H1~G1~H2
   1  2  3

VAR G1=O/S/C/N
NODE ATTRIBUTES:
DEFAULT MLEVEL IS ATOM
DEFAULT ELEVEL IS LIMITED
ECOUNT IS M3-X5 C M1-X3 N AT 1
ECOUNT IS M4-X7 C E1 N AT 3

GRAPH ATTRIBUTES:
RING(S) ARE ISOLATED OR EMBEDDED
NUMBER OF NODES IS 3

STEREO ATTRIBUTES: NONE
L2          19 SEA FILE=REGISTRY SSS SAM L1

0.1% PROCESSED      2000 ITERATIONS      19 ANSWERS
INCOMPLETE SEARCH (SYSTEM LIMIT EXCEEDED)
SEARCH TIME: 00.00.02

FULL FILE PROJECTIONS:  ONLINE  **INCOMPLETE**
                        BATCH    **INCOMPLETE**
PROJECTED ITERATIONS:   32063924 TO 32187076
PROJECTED ANSWERS:      297793 TO 312591
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Thus it is clear that applicant's compound core is not applicant's contribution over the prior art and the commonly shared structure does not constitute a structurally distinctive portion in view of the existing prior art. Thus there is a lack of unity.

A prior art reference anticipating the claims with respect to one group would not render obvious the same claims with respect to another group. Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the

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inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 (a) of the other invention.

Inventions I-VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different rings formed by the combinations of variables  $X_1$ ,  $X_2$ , and  $X_3$ , and the different rings for variable W. If the groups are classified, groups I and II would be classified in class 544, subclass 242, group III in class 546, subclass 1, and IV in class 544, subclass 224 and V in class 544, subclass 336.

Claim 1 is generic to the following disclosed patentably distinct species: groups I-VI. The species are independent or distinct because as disclosed the different species have mutually exclusive characteristics for each identified species. In addition, these species are not obvious variants of each other based on the current record.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be**

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traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species**, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

- (a) the inventions have acquired a separate status in the art in view of their different classification;

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(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

**Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.**

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either

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instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Noble Jarrell whose telephone number is (571) 272-9077. The examiner can normally be reached on M-F 7:30 A.M - 6:00 P.M. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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